REMARKS

Claims 1-19 and 47-51 have been cancelled as being drawn to a non-elected invention. Applicants reserve the right to pursue cancelled Claims 1-19 and 47-51 in a divisional or continuation application. Claims 34-38 have also been cancelled, Claims 20, 26, 31, 39 and 41 have been amended and new Claims 52-55 have been added. Support for new Claims 52-55 can be found throughout the specification, and especially on page 16, line 4 under the heading "Genetically Modified Plants and Methods of Making". Thus, Claims 20-33, 39-46, and 52-55 are presented for examination.

Sequence Listing

The Examiner alleged that the amino acid sequence mentioned on page 15, line 16, and page 43, line 2 did not refer to a SEQ ID Number in the Sequence Listing. Applicants have amended the specification to identify this amino acid sequence as SEQ ID NO: 3. As SEQ ID NO: 3 was part of the Sequence Listing as originally filed with the application, no new matter has been introduced by this amendment. Accordingly, Applicants respectfully submit that the application is in compliance with 37 C.F.R. §§ 1.821-1.825.

Discussion of Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 24-26, 31-33, and 39-46 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants Are Not Invoking 35 U.S.C. § 112, paragraph 6

The Examiner objected to the terms "by physical means" and "by chemical means" in Claims 24 and 25, respectfully. The Examiner argued that Applicants were attempting to use an improper "means" clause since no function was specified by the words preceding "means". Applicants respectfully traverse.

The use of the word "means" in a claim raises a presumption of a means-plus-function claim under § 112, ¶ 6. The presumption of a means-plus function claim can be overcome if either of two conditions are met. A claim is not a means-plus function claim if (1) a claim

element uses the word "means" but recites no function corresponding to the means, or (2) a claim specifies a function but also recites sufficient structure or material for performing that function (Rodime PLC v. Seagate Technology Inc., 174 F.3d 1294, 50 USPQ2d 1429 (Fed. Cir. 1999)).

In the present case, the first condition is readily met and the presumption is overcome. Claims 24 and 25 recite no function corresponding to the means. Accordingly, the presumption that Claims 24 or 25 invoke 35 U.S.C. § 112, ¶ 6 is overcome.

Indeed, Applicants are using the term "means" for its plain and ordinary meaning of "method", as defined in the specification and well-known in the art. For example, on page 24, beginning at line 21, Applicants explain that "contacting" refers to any means of introducing CDR1 into a plant cell, including physical means and chemical means. Clearly, in this case, Applicants are using the term "means" for its ordinary meaning of "method". *See* The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2000 by Houghton Mifflin Company. Several methods for physically contacting a plant cell with a nucleic acid are explained in the specification, such as microinjection (page 24, line 20) or high velocity ballistic penetration (page 24, line 4). An example of a chemical method for contacting a nucleic acid with a plant cell includes the use of polyethylene glycol (page 23, line 22).

As Applicants are using the term "means" for its ordinary meaning of "method", and not to invoke 35 U.S.C. § 112, paragraph 6, Applicants respectfully request withdrawal of this rejection.

Claims 26 and 31-33, 39 and 41 are Not Indefinite

Claims 31-33 were objected to for depending upon non-elected Claim 5. Applicants have amended Claim 31 to remove the dependence on non-elected Claim 5 and therefore respectfully request that this objection be withdrawn.

Claim 26 was objected to for allegedly lacking antecedent basis for the term "the plant cell is". While Applicants respectfully traverse, solely in order to advance prosecution, Claim 26

has been amended to now recite "the plant cells are" as suggested by the Examiner. Accordingly, Applicants respectfully request that this objection be withdrawn.

Claim 39 was objected to for being an incomplete method claim. Applicants respectfully traverse. However, solely to advance prosecution of the application, Applicants have amended Claim 39 to recite that the transformed plant cell is grown under conditions which permit expression of the constitutive disease resistance 1 (CDR1) polypeptide thereby producing a disease resistant plant. Accordingly, Applicants respectfully request that this objection be withdrawn.

Applicants affirm that Claims 44-46 relate to plants, plant tissue and seeds derived from a plant produced by the method of Claim 39.

Claim 41 was objected to for depending upon non-elected Claim 5. Applicants have amended Claim 41 to remove its dependence on non-elected Claim 5 and therefore respectfully request that this objection be withdrawn.

Discussion of Rejections under 35 U.S.C. § 112, First Paragraph

Enablement

The Examiner rejected Claims 20-31 and 34-46 as allegedly not being enabled by the specification. The Examiner argued that while the specification was enabled for producing disease resistant Arabidopsis plants expressing SEQ ID NO: 1, or encoding the amino acid of SEQ ID NO: 2, it did not enable identification of constitutive disease resistance 1 (CDR1) genes from other plant and non-plant species. Applicants respectfully traverse.

Several factors need to be considered to properly determine whether the specification enables one of ordinary skill in the art to practice the claimed invention without undue experimentation (*In re* Wands, 858 F.2d 731, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988)). These factors include: 1) the quantity of experimentation necessary; 2) the amount of direction or guidance presented in the application; 3) the presence or absence of working examples of the invention in

the application; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability in the art; and 8) the breadth of the claimed invention.

It should be noted that a considerable amount of experimentation is permissible, if it is merely routine (*Ex parte* Jackson, 217 U.S.P.Q. 804, 807 (B.P.A.I. 1982). In addition, experimentation can be 'tedious and laborious,' and nevertheless 'routine' (*Ex parte* Erlich 3 U.S.P.Q.2d 1011 (B.P.A.I. 1982). Experimentation requiring only routine optimization or screening has not been held to be undue experimentation because "[e]nablement is not precluded by the necessity for some experimentation such as routine screening" (*In re* Wands).

With respect to factors one, two and three, the quantity of experimentation necessary, the amount of direction or guidance presented in the application; and the presence or absence of working examples of the invention in the application; the specification discloses with great specificity how to obtain nucleic acids encoding homologs of CDR1 polypeptides, and little experimentation is necessary. For example, Applicants teach how to obtain homologs of CDR1 nucleotides in the section entitled "Screen for Identifying Novel Disease Resistance Genes" (page 27, line 20 to page 28, line 32). Contrary to the Examiner's assertions, this section teaches how to use fragments of SEQ ID NO: 1 to identify other CDR1 family members from cDNA or genomic libraries. Inserting DNA encoding CDR1 polypeptides into a variety of expression vectors is discussed on page 10, line 1 through page 11, line 21. In addition, in the sections entitled "Genetically Modified Plants and Methods of Making" and "Screen for Identifying Novel Disease Resistance Genes" (page 16, line 5 to page 28, line 32), Applicants teach a variety of methods for producing and screening for plants exhibiting increased disease resistance. As Applicants have already discovered that SEQ ID NO: 1 from Arabidopsis provides disease resistance, one would not need to perform activation tagging to identify CDR1 variants in other plants as argued by the Examiner. One of ordinary skill in the art could follow the teachings of the specification to determine homologous genes in other plants, and use that information to isolate CDR1 homologs from those plants. While some routine laboratory work may be needed to obtain nucleic acids, other than SEQ ID NO: 1, which encode CDR1 polypeptides from other plant species, an undue amount of experimentation is not needed. Accordingly, the amount of

guidance provided by the specification is very high. Moreover, actual working examples of transforming and screening a large number of plants are provided by the specification. Thus, these factors also fall in favor of the Applicants.

With respect to factors four and five, the nature of the invention and the state of the prior art; one of skill in the art would be able to practice the claimed invention without undue experimentation. The nature of this invention relates to genetically modified plants, seeds, and methods of making such plants by transformation with a nucleic acid that encodes a CDR1 polypeptide. While plant biology may be complex, the actual methods of discovering homologs of SEQ ID NO: 1, and transforming and screening plants in order to generate genetically modified plants are well-known and practiced by skilled molecular plant biologists. Furthermore, the prior art is replete with a variety of techniques for producing genetically modified plants and numerous references describing transformed plants. Accordingly, this factor falls in favor of the Applicants.

With respect to factor six, the relative skill of those in the art, obtaining variants of known genes, such as SEQ ID NO:1, and screening hundreds, or even thousands, of transformed plants is well within the skill of the ordinary plant molecular biologist. In order to practice the claimed methods directed to producing plants exhibiting increased resistance to disease, one would only need to grow such transformed plants and then screen for those plants with an increased disease resistance. Accordingly, while the quantity of experimentation for such a screen may be high, it would nonetheless be routine experimentation. This factor, therefore falls in favor of the Applicants.

With respect to factor seven, the predictability or unpredictability in the art, as is known and well documented, the level of skill in the area of biotechnology is quite high. And although some areas of biotechnology may be unpredictable, methods of finding gene homologs, and transforming and screening plants are not unpredictable. This is especially true when, as in the present case, one has already discovered the function of a particular gene (SEQ ID NO: 1), and now only needs to screen for homologous genes in other plants that exhibit the known function. Thus, this factor falls in favor of the Applicants.

With respect to factor eight, the breadth of the claimed invention, Applicants claims are well within the scope of the disclosure. Applicants are only claiming genetically modified plants, seeds, and methods of making such plants by transformation with a nucleic acid that expresses a CDR1 polypeptide. CDR1 polypeptides are defined as including sequences substantially the same as the sequence set forth in SEQ ID NO: 2 (page 7, line 5). The term "substantially the same" refers to variants of SEQ ID NO: 2 that retain the activity of CDR1 for conferring disease resistance to plants. CDR1 polypeptides are also defined to include conservative variations of SEQ ID NO: 2. Conservative variations are defined as denoting replacement of an amino acid residue by another, biologically similar residue (page 7, line 9). One of ordinary skill in the art can easily know the metes and bounds of such a claim by reference to the specification and SEQ ID NO: 2. Moreover, it would only require routine experimentation to screen plants transformed with nucleic acids encoding a CDR1 polypeptide to determine which plants exhibited an increased resistance to disease. Thus, this factor falls in favor of the Applicants.

By application of the Wands factors, it is clear that undue experimentation is not required to make and use the claimed invention. Thus, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, and allowance of the pending application.

The Examiner also argued that the specification did not enable methods of producing disease resistant plants by contacting susceptible plants with a CDR1 promoter inducing an amount of an agent to elevate CDR1 gene expression, as recited in Claims 34-38. Applicants respectfully traverse. However, Claims 34-38 have been cancelled, thus rendering this rejection moot.

The Examiner also alleged that the specification was only enabling for production of transgenic plants that were resistant to bacterial diseases, but did not enable transgenic plants with increased resistance to all known pathogens. Applicants respectfully traverse.

The specification teaches that transforming a plant with a nucleic acid encoding a CDR1 polypeptide resulted in increased resistance to pathogens, such as bacteria (page 39, Example 10). As recited in the specification, transformation of such a nucleic acid can provide increased

resistance to a variety of agents including, but not limited to, bacteria, nematodes, viruses, mycoplasmas and fungi (page 16, line 14). Applicants have specifically demonstrated that plants transformed with a nucleic acid encoding a CDR1 polypeptide exhibit an increased resistance to a number of bacterial pathogens. Thus, it would not require undue experimentation for one of ordinary skill in the art to test such transformed plants for resistance to a variety of other pathogens. And although the CDR1 transformed plants may not be resistant to every possible plant pathogen, Applicants have nonetheless fully described how to screen for CDR1 transformed plants that are resistant to numerous types of pathogens (page 16, line 5 to page 17, line 18). Applicants note that they are entitled to claim the genus of plant pathogens even though some species of this genus may be inoperable (*In re* Wands). For these reasons, Applicants respectfully request withdrawal of this rejection.

Written Description

The Examiner rejected Claims 20-30, 34-40 and 42 under 35 U.S.C. § 112, first paragraph as allegedly not complying with the written description requirement. The Examiner argued that Applicants had not described the structure of other nucleic acids encoding a CDR1 polypeptide, or a CDR1 promoter inducing agent, or a transcription factor for CDR1 gene expression. Applicants respectfully traverse.

In order to meet the written description requirement, Applicants are only required to show that their patent application describes the claimed invention in sufficient detail so that one of ordinary skill in the relevant art would conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, (Fed. Cir. 1991).

In this case, the claimed invention relates to genetically modified plants, seeds, and methods of making such plants by transformation with a nucleic acid that encodes a CDR1 amino acid sequence. Applicants' specification provides specific evidence that the inventors were in possession of this invention. For example, the specification provides detailed information on the identification and sequence analysis of a CDR1 cDNA (SEQ ID NO: 1) and a CDR1 amino acid (SEQ ID NO: 2) (page 6, line 1 to page 11, line 21). Methods of identifying homologs of CDR1

are described on page 27, beginning on line 20. Furthermore, the specification provides a complete and detailed description of methods for producing genetically transformed plants having increased disease resistance (page 16, line 4 to page 18, line 23; and Example 14, page 41).

Accordingly, Applicants have described the claimed invention in sufficient detail so that one of ordinary skill in the relevant art would conclude that they were in possession of the claimed invention at the time the application was filed.

The Examiner argued that the specification did not provide an adequate written description of methods for producing disease resistant plants by contacting susceptible plants with a CDR1 promoter inducing amount of an agent to elevate CDR1 gene expression, as recited in Claims 34-38. Applicants respectfully traverse. However, Claims 34-38 have been cancelled, thus rendering this rejection moot.

Applicants therefore request the withdrawal of the written description rejection and allowance of the pending claims.

Discussion of Rejections under 35 U.S.C. § 102

The Examiner rejected Claims 20-30, 39-40 and 42-46 as allegedly being anticipated by Ryals (U.S. 5,614,395). The Examiner argued that neither the specification nor the claims provided limitations that distinguish a nucleic acid encoding a CDR1 polypeptide from other nucleic acids encoding unrelated polypeptides having constitutive disease resistance activity. Applicants strongly disagree.

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of

ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Applicants point out that each of the claims recite contacting plants with a "nucleic acid encoding a constitutive disease resistance 1 (CDR1) polypeptide." The term "CDR1 polypeptide" has a specific meaning, and is particularly defined in the specification. For example, CDR1 polypeptides are defined as including sequences substantially the same as the sequence set forth in SEQ ID NO: 2 (page 7, line 5). The term "substantially the same" is defined as referring to amino acid sequences that retain the activity of CDR1 for conferring disease resistance to plants. CDR1 polypeptides are also defined to include conservative variations of the SEQ ID NO: 2. Conservative variations are defined as denoting replacement of an amino acid residue by another, biologically similar residue (page 7, line 9). Thus, nucleic acids that encode a CDR1 polypeptide do not encompass every nucleic acid molecule that encodes a protein having the function of constitutive disease resistance. Only those nucleic acids that encode a CDR1 polypeptide, as defined in the specification, are within the scope of the claims.

Accordingly, as Ryals, et al. do not teach production of disease resistance plants by transformation with a nucleic acid encoding a CDR1 polypeptide, as claimed, Ryals, et al. do not anticipate Claims 20-30, 39-40 and 42-46. For this reason Applicants respectfully request withdrawal of this rejection, and allowance of the pending claims.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: March 2, 2004

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